REMARKS

Claims 1-16 and 27-55 are pending. Claims 1, 7, 10, 14, 27, 31, 38, 41, 47, and 50 have been amended to remove unelected subject matter from the claims. Applicants reserve the right to prosecute subject matter withdrawn from consideration by cancellation or amendment in one or more continuation, continuation-in-part, or divisional applications. The claims are fully supported by the instant specification thus no new matter has been added to the claims.

Claim Objections

Claims 1, 7, 10, 14, 27, 31, 38, 41, 47, and 50 are objected to for reciting non-elected sequences. The claims have been amended to delete such recitals.

Rejections Under §112

Claims 1-3, 7-16, 27-34, 38-43, and 47-52 are rejected under 35 U.S.C. §112, first paragraph as not being enabled by the specification. The Examiner alleges that the specification does not enable a person skilled in the relevant art to make and/or use the invention commensurate with the scope of the claims. Applicants respectfully disagree.

The Examiner argues that the specification does not teach which residues can be substituted with which nucleotides and thus does not enable the presently claimed nucleic acids. Furthermore, the Examiner cites US Patent No. 5,670,706 to demonstrate that not all chitinases have activity against living fungi. Consequently, the Examiner concludes that the members of the claimed genus of nucleic acid molecules may encode chitinases with different levels of anti-fungal activity as compared to each other or SEQ ID NO:1.

The claimed nucleic acids are described by both structural and functional features. Structural limitations are imposed on nucleic acid molecules by the claims such that

each member of the claimed genus must have a nucleotide sequence that encodes a polypeptide that is at least 91% identical to SEQ ID NO:12 or has the ability to hybridize to a nucleic acids molecule that encodes SEQ ID NO:12. The claims also require that the nucleic acid molecules encode a chitinase polypeptide and/or a polypeptide with chitinase activity and thus impose a functional limitation on the encoded polypeptide. The instant specification discloses a number of methods to measure chitinase activity. For example, the ability of a polypeptide to hydrolyze chitin can be measured (*e.g.*, see Example 2 of the instant specification) as well as its ability to inhibit fungal growth (*e.g.*, as disclosed in Examples 3-5 of the instant specification). These straightforward assays provide an easy way to determine if a candidate nucleic acid molecule that meets the structural features (*i.e.*, nucleotide sequence) required by the claims also meets the functional limitations (*i.e.*, chitinase activity). Thus, the members of the claimed genus are enabled sufficiently by the specification.

The functional claim limitation is that the encoded polypeptide have chitinase activity, not that it has activity identical to that of SEQ ID NO:12. As such, any chitinase activity is sufficient and thus the nucleic acid molecules of the claimed genus may have different levels and types of activities and still be encompassed.

Furthermore, Applicant is under no duty to ensure that every nucleic acid molecule encompassed by one claim limitation meets the other limitations. For example, there may be a number of nucleic acid molecules that encode a polypeptide that is at least 91% identical to SEQ ID NO:12 (and thus meet the structural limitation of the claim) that do not have chitinase activity. Such nucleic acids are not encompassed by the claims because they to not meet the functional limitation of the claim. A claim can be valid even if there are non-working embodiments. "It is not a function of the claims to specifically exclude . . . possible inoperative substances . . . " *Atlas Power Co. v. E. I. Du Pont de Nemours & Co.*,

750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984) citing *In re Dinh-Nguyen*, 492 F.2d 856, 858-859, 181 USPQ 46, 48 (CCPA 1974)(emphasis omitted).

Applicants have provided a number of simple assays that one skilled in the art can use to distinguish between those polypeptides that have chitinase activity and those that do not. The procedures used in order to generate nucleic acid molecules that meet the structural claim limitations and the same to see if the functional claim limitation is met are routine molecular biological techniques that the skilled artisan is thoroughly familiar and thus would not be undue. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (B.P.A.I. 1982) ("[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine."). *Ex parte Erlich* 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982) (observing that although a method might be 'tedious and laborious,' such experimentation is nevertheless 'routine').

Additionally, the Examiner contends that transgenic plants comprising a nucleic acid molecule of the invention are not taught by the specification. Applicants contend that at the time of filing, production of transgenic plants in general was well known in the art. As such, one skilled in the art could produce a transgenic plant containing a nucleic acid molecule of the invention and adjust the protocol to accommodate expression of the chitinase polypeptide. Information which is well known in the art need not be described in detail in the specification. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80 (Fed. Cir. 1986).

It is not necessary to provide examples that encompass the entire realm of any and all species in a claimed genus. See *In re Bowen*, 492 F.2d 859, 181 U.S.P.Q. 48 (C.C.P.A. 1974). Accordingly, there appears to be no basis for the non-enablement rejection on the theory that claims read on undisclosed and untested nucleic acid molecules. While the

claims literally comprehend numerous nucleic acid molecules in addition to the ten specifically described in specification (SEQ ID NOS:24, 30, 34, 38, 46, 48, 60, 62, 66, and 72 are all at least 91% identical to SEQ ID NO:12, *see infra*) no persuasive reason has been given by the Patent Office as to why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed. All the Examiner has done is to point out that the Applicants did not provide examples for every species that might be encompassed by the present claims. According to applicable case law, an inventor is not required to disclose "a test of every species encompassed by their claims" even in an unpredictable art. *In re Angstadt*, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976) (emphasis in original). An invention is enabled even though the disclosure may require some routine experimentation to practice the invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 U.S.P.Q. 81, 94 (Fed. Cir. 1986).

Claims 1-3, 14-16, 31-34, 41-43, and 50-52 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner alleges that Applicants did not describe the claimed subject matter in such a way as to convey to the skilled artisan that they had possession of the claimed invention. Applicants respectfully disagree.

The Examiner alleges that Applicants have not adequately described the genus of nucleic acid molecules claimed. Applicants contend that at least ten members of the genus of nucleic acid molecules that encode a chitinase polypeptide that is at least 91% identical to the polypeptide encoded by SEQ ID NO:11 have been disclosed in the instant specification. Specifically, SEQ ID NOS:30 and 34 are 99% identical to SEQ ID NO:12; SEQ ID NOS:48, 60, and 72 are 95% identical to SEQ ID NO:12;. SEQ ID NOS:46 and 62 are 94% identical to

SEQ ID NO:12; SEQ ID NOS:38 and 66 are 93% identical to SEQ ID NO:12; and SEQ ID NO:24 is 92% identical to SEQ ID NO:12 (see Figure 1 submitted with the Response To Restriction Requirement filed May 3, 2005. Nucleic acid molecules encoding each of SEQ ID NOS:24, 30, 34, 38, 46, 48, 60, 62, 66, and 72 are disclosed in the instant specification as SEQ ID NOS: 23, 29, 33, 37, 45, 47, 59, 61, 65, and 71, respectively.

Additionally, polypeptides of SEQ ID NOS:30, 34, 38, 46, 48, 60, 62, 66, and 72 were shown to have improved anti-fungal activity in comparison to wild type chitinase A (SEQ ID NO:1). The data in Table 4 in the instant specification shows that polypeptide of SEQ ID NO:72 had a 23.7 fold increase in activity over wild type chitinase. The data in Table 5 in the instant specification shows that polypeptide of SEQ ID NOS:30, 34, and 38 had a 2.8, 3.5, and 8.0 fold increase in activity over wild type chitinase, respectively. The data in Table 6 in the instant specification shows that polypeptide of SEQ ID NOS:46, 48, 60, 62, and 66 had a 23, 17, 21, 18, and 19 fold increase in activity over wild type chitinase, respectively. This is well above the 20% or 200% (*i.e.*, 2 fold) activity of SEQ ID NO:1 that is required by some of the dependant claims.

Applicants contend that the claimed nucleic acids have been described both structurally as well as functionally (see *supra*) and as such have met the written description requirements.

Recently, the United States Court of Appeals for the Federal Circuit held that each claim, broad and specific, must be examined taking into account a variety of factors including knowledge in field, extent and content of prior art, maturity of science and technology, predictability of aspect at issue and "other considerations appropriate to subject matter" *Capon et al. v Eshhar, et al.*, U.S. App LEXIS 16865 (Fed. Cir. Aug. 12, 2005) Accordingly, recitation of nucleic acids encoding a polypeptide at least 91% identical to SEQ

ID NO:12 coupled with the enabling examples and corresponding written description in view of the state of the art should be considered sufficient to describe the claimed subject matter.

In view of the foregoing, applicants respectfully request that the rejections under 35 U.S.C. § 112 are reconsidered and withdrawn.

CONCLUSION

It is believed that the claims are in condition for allowance. Early and favorable action by the Examiner is earnestly requested.

AUTHORIZATION

No fee is believed due. However, the Commissioner is hereby authorized to charge any fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2119-4280.

Respectfully submitted,
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